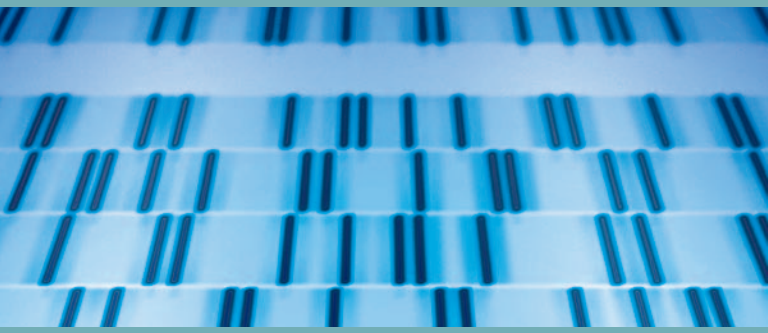


Translational Research

WHAT IS IT?

WHY IS IT IMPORTANT TO ARIZONA?

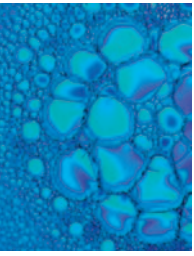
SHAPING THE NEW MODEL OF TRANSLATIONAL RESEARCH

While impressive progress has been made in basic research science in recent years, real-world technologies based on these discoveries have often failed to materialize in the marketplace. This has highlighted flaws in the traditional system responsible for translating basic research into practical health and economic benefits. Revamping this system has become a national imperative, and for Arizona, a statewide priority.

While recent advances in bioscience research are unparalleled, the system of translating this knowledge to products is failing.

"BENCH TO BEDSIDE"

Each practical solution to a biomedical problem – drug, vaccine, diagnostic device – begins as an initial design sparked in the imagination of one or more "translators" from an evaluation of basic research knowledge. While there is no set path from basic "bench" research to clinical "bedside" result, there are some commonalities: design, early-stage development, testing in a simplified system (pre-clinical trial), human testing (clinical trial), risk evaluation, and approval.



The translators in this process are many and varied – chemists, molecular biologists, medical technologists, marketing analysts, clinicians, policymakers, federal agencies, review panels. The translation also moves

DEFINING TRANSLATIONAL RESEARCH

The process of applying knowledge gained through basic scientific research to practical applications in medicine for purposes of improved patient care.

from bedside back to bench – each stage feeds back new information to translators working at earlier stages in the process, allowing new solutions to be funneled back into the pipeline toward a successful clinical application.

Efficient translation requires a shared language. Disparate training, culture, and rules governing this array of professionals and agencies have resulted in a bottleneck prompting a call by the National Institutes of Health for "reengineering the clinical research enterprise."

WHY IS THIS IMPORTANT TO ARIZONA?

Arizona is developing a new model of translational research to strengthen its long-term plan to become nationally competitive in the biosciences, known as *Arizona's Bioscience Roadmap*. The model also creates an opportunity for Arizona to stake a national leadership claim in this vital field by pioneering new approaches to moving discoveries forward.

The NIH and FDA have launched major initiatives to address the translational gap.

Efficient translational research would fortify the *Roadmap*'s core platform areas of neurological sciences, cancer therapeutics, bioengineering, and bioimaging. It also would enhance efforts to attain bottom-line *Roadmap* outcomes:

- **Economic benefits** More post-development technologies means increased jobs and business opportunities to support all stages of production, marketing, and distribution.
- **Federal Grants** The NIH focus on increased translational research means greater grant funding to those states and projects "doing it right."
- **Healthcare** Arizonans will have greater access to cutting-edge medical treatments being developed locally.

WHERE DOES ARIZONA STAND?

Arizona's relative newness to this playing field is both an obstacle and opportunity. It currently lacks the infrastructure required to compete with regions that have institutes and medical centers with long-standing traditions in basic research and clinical excellence. However, Arizona is less entrenched in the old system and therefore positioned to tear down barriers to collaboration and innovation.

Translational research offers an opportunity for Arizona to "leapfrog" into national prominence in bioscience innovation.

The *Roadmap* gives Arizona a distinct advantage. It has identified Arizona's core research strengths and brought together leading researchers from statewide public and private institutions to guide this research. The *Roadmap* has set the stage with a spirit of collaboration, coalescing leaders in business, medicine, research, and policy in a shared vision of the state's bioscience future.

WHAT WILL IT TAKE?

Arizona's success in translational research requires a collaborative, multidisciplinary approach. The array of individuals, institutes, and agencies involved in all stages of translational research must bridge gaps in training and culture. The current system must be retooled so that both the mechanism and culture of collaboration are in place to overcome barriers to success. This is particularly important between the basic scientific researcher and the practicing clinician.

Arizona's track record in collaboration provides a distinct, important advantage.

To this end, four *Roadmap* committees and workgroups met throughout 2005 to develop a translational research model. The panels are represented by experts from universities, research institutes, teaching hospitals, medical centers, law, bioscience industry, and government. They are addressing ways that institutions can share information, link researchers and clinicians, streamline the review process for clinical trials, and other steps to heighten collaboration and successful outcomes. The project is funded by the Flinn Foundation and Arizona Biomedical Research Commission. The final report, to be prepared by Battelle, will be issued in 2006.

ARIZONA BIOMEDICAL RESEARCH COMMISSION

Arizona's assets in translational research include a growing patient population and medical system, excellence in areas of technology tied to bioscience innovation, a statewide strategic plan, and a strong track record of collaboration across institutions. One organization that has taken a leadership role in facilitating collaboration is the Arizona Biomedical Research Commission (ABRC), known until recently as the Arizona Disease Control Research Commission.

This state agency has funded nearly $100 million to Arizona medical researchers and clinicians since its inception in 1985. Its funding comes largely through tobacco taxes and other publicly dedicated revenues. In 2005, ABRC changed its name and primary focus to support multidisciplinary, collaborative projects within the core-competency areas identified by *Arizona's Bioscience Roadmap*. The Commission meanwhile continues to provide its traditional funding for new investigators.

In addition to its broader funding mandate, the Commission supports translational research projects and helps to lead Arizona's planning efforts in this area. Following are three examples of representative grants:

- **Arizona Parkinson's Disease Center** The Center creates a three-year collaboration bringing together leading investigators throughout the state in the study of Parkinson's Disease, an extremely debilitating neurologic disorder affecting the aged population. Researchers at the Center study early predictors of the

disease and investigate the possibility of molecular targets for therapy. The Center pools research talent from Sun Health Research Institute, Mayo Clinic, Barrow Neurological Institute, Banner Good Samaritan Medical Center, Arizona State University, and the Translational Genomics Research Institute (TGen), and serves to support the *Roadmap* neurological sciences platform area.

■ **Arizona Bio-Specimen Alliance** The Alliance recognizes the state's need to create infrastructure in the form of centralized banks of patient samples. These banks of tissue and other bio-specimen samples increase availability to all institutions for experimentation. The Alliance also provides a standard sample quality that directly impacts research results. Founded by the Molecular Profiling Institute, TGen, International Genomics Consortium, Scottsdale Healthcare, and Sun Health Research Institute, the Alliance will be responsible for standardizing and streamlining the process for sample collection, processing, storage, and tracking.

■ **System for Collaborative Translational Research** Collaboration is vital for scientific discovery and validation but often information technology can impede rather than advance progress. This project has developed a standardized computer platform that enables the collection, storage, analysis, monitoring, integration, and sharing of clinical and genomic research data. Results can be utilized by research collaborators located across geographic boundaries, in diverse disciplines, and using a variety of information technology systems. By improving the flow of information among collaborators, the translation of biomedical research to patient application will be enhanced.

The following organizations are represented on the Translational Research Project Advisory Committee of *Arizona's Bioscience Roadmap* and its three workgroups.

- Arizona Biomedical Research Commission
- Arizona Medical Association
- Arizona State University
  - Biodesign Institute at ASU
  - College of Nursing
  - Harrington Department of Engineering
  - Office of General Counsel
  - W.P. Carey School of Business
- Arizona Supreme Court
- Banner Health
- Barrow Neurological Institute at St. Joseph's Hospital & Medical Center
- Battelle
- Carl Hayden VA Medical Center
- Catholic Healthcare West
- Coppersmith, Gordon, Schermer, Owens & Nelson, PLC
- Flinn Foundation
- Gila River Indian Community
- International Genomics Consortium
- Lewis & Roca, LLP
- Maricopa Medical Center
- Mariposa Community Health Center
- Mayo Clinic
- Molecular Profiling Institute
- Northern Arizona University
  - Biological Sciences Department
  - Environmental Education Outreach Program
  - Office of Grant & Contract Services
- Office of the Attorney General
- Office of the Governor
- Phoenix Children's Hospital
- St. Joseph's Hospital & Medical Center
- Scottsdale Healthcare
- Southern Arizona VA Healthcare System
- Sun Health Research Institute
- Translational Genomics Research Institute
- University of Arizona
  - Arizona Cancer Center
  - Arizona Cancer Center, Greater Phoenix Area
  - Arizona Health Policy and Law Institute
  - Arizona Health Sciences Center
  - Arizona Research Labs
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  - College of Medicine
  - College of Medicine, Phoenix
  - College of Public Health
  - Legal Affairs & General Counsel
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